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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/817,230      | 04/02/2004  | Victor I. Chormenky  | 1004.013            | 3048             |

7590  
Law Offices.  
P.O. Box 386353  
Bloomington, MN 55438

01/14/2008

| EXAMINER |
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GILBERT, ANDREW M

| ART UNIT | PAPER NUMBER |
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3767

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01/14/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/817,230

Applicant(s)

CHORNENKY ET AL.

Examiner

Andrew M. Gilbert

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 29 October 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-8 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-8 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 02 April 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.

- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Acknowledgments***

1. This office action is in response to the reply filed on 10/29/2007.
2. In the reply, claim 1 was amended.
3. Thus, claims 1-8 are pending for examination on the merits.

### ***Claim Rejections - 35 USC § 112***

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 1 recites: "wherein the movement of the delivery apparatus from the inactive position to the operational position causes said needle tip to deform said needle ..." (emphasis added). The needle tip cannot deform the needle. The needle tip is a portion of the needle. Rather, the Examiner believes the applicant intended to recite that the distal probe end of the elongate probe causes the needle to deform as it moved from the inactive to the operational position. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 103***

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 1-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Paques et al (2002/0087128) in view of Flaherty et al (6544230). Paques et al discloses Paques et al discloses a minimally invasive therapeutic agent delivery system (Fig 1) comprising a reservoir (10) comprising a therapeutic agent (Fig 4, [0020, 0039, 0041, 0058]); an elongate probe (2) having a passage therein, the probe configured to conform to provide a substantially linear portion (LA2; Fig 2, 4) and a portion that conforms at least in part to the curvature of the eye (LA1; Fig 2, 4) and has a proximal probe end (2p) and a distal probe end (2d) including a distal probe opening (Fig 1, 2d); a therapeutic agent delivery apparatus (Fig 1) comprising a needle having a sharp tip (4, 4a) configured to pierce the sclera to a predetermined depth (wherein the Examiner notes that the device is fully capable of piercing to a predetermined depth under control of the user), and the said needle being fluidly connected to said reservoir (Fig 1, 4, [0040-0041) and configured to be disposed within said passage (Fig 1) and movable between a retracted inoperative position within said probe ([0021, 0023, 0028-0030, 0039-0044, 0058]) and an extended operational position ([0021, 0023, 0028-0030, 0039-0044, 0058]), wherein movement of said delivery apparatus from the inactive to the operational position causes said needle to pierce the sclera to a predetermined position (Fig 1, [0021, 0023, 0028-0030, 0039-0044, 0058]) and enables the therapeutic agents to be dispensed from said reservoir through said needle into the eye ([0021, 0023, 0028-0030, 0039-0044, 0058])); a handle (2a, 2p) attached to said probe proximal end (2a, 2p, Fig 1, 4); the reservoir being attached to said handle (Fig 1, [0041]); the therapeutic agent delivery apparatus comprises an elongate needle (4); and said probe

includes a probe positioning portion (2d) at said distal probe end; the elongate probe configured to conform at least in part to the curvature of the eye (Fig 1, 4, [0021, 0023, 0028-0030, 0039-0044, 0058]) and the probe distal end having an eye-surface engaging surface (2d, Fig 1, 4), the probe passage including a portion conforming to the surface of the eye (2d, Fig 1, 4) and a portion that angles toward the eye such that said distal probe opening is in said eye-surface engaging surface (4, 2d, Fig 1, 4).

8. However, Paques et al does not expressly disclose wherein the movement of the delivery apparatus from the inactive position to the operational position causes the distal probe end to deform said needle.

9. Flaherty et al teaches that it is known to have a elongate member (12) having a passage bend a piercing needle (30, 30d, Fig 7) when said needle is moved from its retracted to its extended position (Fig 10a, 10f) for the purpose of controlling and enhanced aiming of the needle member so it will remain inside a preferred place or acceptable penetration zone as it is advanced (col 11, Ins 24-67)

10. Flaherty et al teaches that it is known to have wherein the movement of the delivery apparatus (30) from the inactive position (Fig 10f) to the operational position (Fig 10a) causes the distal probe end (60, 16; Fig 10a, 10f) to deform said needle (30; col 11, Ins 24-67; col 12; Ins 40-67) for the purpose of controlling and enhanced aiming of the needle member so it will remain inside a preferred place or acceptable penetration zone as it is advanced (col 11, Ins 24-67). Flaherty et al teaches that deforming the needle as it moves from inoperational (Fig 10f) to operational (Fig 10a) results in an improved ability to constrain the piercing member within a desired

penetration zone giving a more precise positioning of the piercing needle. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the elongate probe as taught by Paques et al with the distal probe end as taught by Flaherty et al for the purpose of controlling and enhanced aiming of the needle member so it will remain inside a preferred place or acceptable penetration zone as it is advanced (col 11, lns 24-67).

### ***Response to Arguments***

11. Applicant's arguments with respect to claims 1-8 have been considered but are moot in view of the new ground(s) of rejection.

### ***Conclusion***

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Andrew M. Gilbert whose telephone number is (571) 272-7216. The examiner can normally be reached on 8:30 am to 5:00 pm Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571)272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
Andrew Gilbert

KEVIN C. SIRMONS  
SUPERVISORY PATENT EXAMINER

